



IFW

PTO/SB/21 (04-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/758,401
	Filing Date	January 15, 2004
	First Named Inventor	G. Mike Makrigiorgos
	Art Unit	To be assigned
	Examiner Name	To be assigned
Total Number of Pages in This Submission	Attorney Docket Number	700157-53471

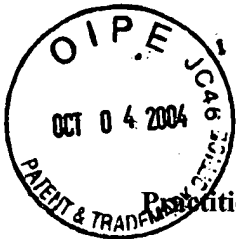
ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input checked="" type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	Certificate of Mailing; References C1-C18; and Return Receipt Postcard
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<b>Remarks</b> The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment to the Nixon Peabody LLP Deposit Account No. 50-0850.	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Ronald I. Eisenstein (30,628)/Nicole L.M. Valtz (47,150) Nixon Peabody, LLP, 100 Summer Street, Boston, MA 02110
Signature	<i>Nicole L. Valtz</i>
Date	Sept. 30, 2004

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.		
Typed or printed name	(Linda M. Ginsberg)	
Signature	<i>[Signature]</i>	Date 9/30/2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Applicant's Docket No. 700157-53471

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: G. Mike Makrigiorgos

Application No.: 10/758,401

Group No.: To be assigned

Filed: 01/15/2004

Examiner: To be assigned

For: AMPLIFICATION OF DNA IN A HAIRPIN STRUCTURE, AND APPLICATIONS

**MAIL STOP AMENDMENT**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)**

I hereby certify that the attached correspondence comprising:

1. Certificate of Mailing (1 pg.);
2. Change of Attorney's Address (1 pg.)
3. Transmittal Form PTO/SB/21 (1 pg.);
4. Information Disclosure Statement with Form PTO/SB/08b (4 pp.);
5. COPY-References C1-C18; and
6. Return Receipt Postcard.

is being deposited with the United States Postal Service, with sufficient postage, as first class mail in an envelope addressed to:

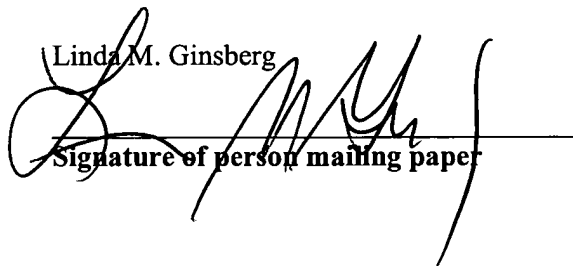
**MAIL STOP AMENDMENT**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

on September 30, 2004.

Linda M. Ginsberg  
  
Signature of person mailing paper



Practitioner's Docket No. 700157-53471

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: G. Mike Makrigiorgos

Application No.: 10/758,401

Group No.: To be assigned

Filed: 01/15/2004

Examiner: To be assigned

For: AMPLIFICATION OF DNA IN A HAIRPIN STRUCTURE, AND APPLICATIONS

MAIL STOP AMENDMENT

Commissioner for Patents

P. O. Box 1450

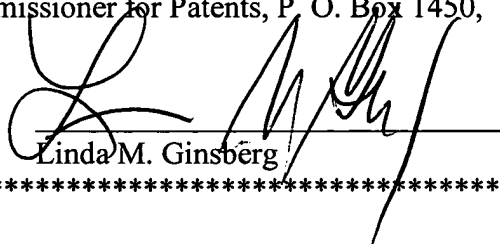
Alexandria, VA 22313-1450

\*\*\*\*\*

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is, on the date shown below, being: deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Date: September 30, 2004

  
Linda M. Ginsberg

\*\*\*\*\*

Sir:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with the provisions of 37 C.F.R. §§1.56 and 1.97, Applicants herewith submit the publications and/or patents shown on the attached form PTO/SB/08b, for consideration by the Examiner in connection with the examination of the above-identified patent application.

**I. REMARKS**

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

X (1) within three (3) months of the Filing Date or **before the mailing date of the First Office Action** on the merits; or

- (2) within three months of the mailing date of the PCT International Search Report; or
- (3) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or
- (4) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

It is respectfully requested that each of the documents shown on the attached form(s) PTO/SB/08b be made of record in this application. Copies of these documents (CHECK ONE):

  X   are enclosed herewith; and

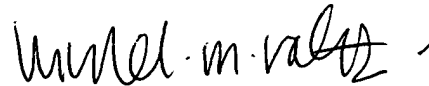
— have been cited in the parent application, and are thus not being resubmitted herein.

Early examination and allowance of the present application are respectfully solicited.

#### **FEE AUTHORIZATION**

Should any fees associated with the submission be required, the Commissioner is authorized to charge the missing fee to our Deposit Account No. 50-0850. Any overpayments should be credited to said Deposit Account.

Respectfully submitted,



Ronald I. Eisenstein (Reg. No. 30,628)  
Nicole L.M. Valtz (Reg. No. 47,150)  
NIXON PEABODY LLP  
100 Summer Street  
Boston, MA 02110  
(617) 345-6054

Date: September 30, 2004



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	10/758,401
Filing Date	01/15/2004
First Named Inventor	G. Mike Makrigiorgos
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	700157-53471

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	PAULO ANDRE ET AL., "Fidelity and Mutational Spectrum of Pfu DNA Polymerase on a Human Mitochondrial DNA Sequence," Genome Research, Vol. 7, p. 843-852, (1997).	
	C2	BARTRAM, C.R. ET AL, "Detection of minimal residual leukemia by polymerase chain reactions," Bone Marrow Transplant, p. 4-8, (1990).	
	C3	NEAL F. CARIELLO ET AL., "Fidelity of Thermococcus litoralis DNA polymerase (Vent) in PCR determined by denaturing gradient gel electrophoresis," Nucleic Acids Research, Vol. 19 ( No. 15), p. 4193-4198, (July 1, 1991).	
	C4	AIMEE L. JACKSON ET AL., "On the origin of multiple mutations in human cancers," Seminars in Cancer Biology, Vol. 8, p. 421-429, (1998).	
	C5	GARETH J.S. JENKINS ET AL., "Mutation analysis using the restriction site mutation (RSM) assay," Mutation Research, Vol. 405, p. 209-220, (1998).	
	C6	MANJIT KAUR ET AL., "Ligation of a primer at a mutation: a method to detect low level mutations in DNA," Mutagenesis, Vol. 17 ( No. 5), p. 365-373, (2002).	
	C7	PHOUTHONE KEOHAVONG, "Fidelity of DNA polymerases in DNA amplification," Proc. Natl. Acad. Sci. USA, Vol. 86, p. 9253-9257, (December, 1989).	
	C8	KONSTANTIN KHRAPKO ET AL., "Mutational spectrometry without phenotypic selection: human mitochondrial DNA," Nucleic Acids Research, Vol. 25 ( No. 4), p. 685-693, (1997).	
	C9	XIAO-CHENG LI-SUCHOLEIKI ET AL., "A sensitive scanning technology for low frequency nuclear point mutations in human genomic DNA," Nucleic Acids Research, Vol. 28 ( No. 9), p. E44, (2000).	
	C10	QIANG LIU ET AL., "Truncated Amplification: A Method for High-Fidelity Template-Driven Nucleic Acid Amplification," BioTechniques, Vol. 33 (No.1) p. 129-138, (July, 2002).	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/758,401
				Filing Date	01/15/2004
				First Named Inventor	G. Mike Makrigiorgos
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	2	of	2	Attorney Docket Number	700157-53471

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C11	PAGE B. MCKINZIE ET AL., "Prospects for applying genotypic selection of somatic oncomutation to chemical risk assessment," Mutation Research, Vol. 489, p. 47-78, (2001).	
	C12	HISAYOSHI NAKAZAWA ET AL., "Relationship Between Chemcially Induced Ha-ras Mutation and Transformation of BALB/c 3T3 Cells: Evidence of Chemical-Specific Activation and Cell Type-Specific Recruitment of Oncogene in Transformation," Molecular Carcinogenesis, Vol 3, p. 202-209, (1990).	
	C13	BARBARA L. PARSONS ET AL., "Genotypic selection methods for the direct analysis of point mutations," Mutation Research, Vol. 387, p. 97-121, (1997).	
	C14	BARBARA L. PARSONS ET AL., "Detection of Basepair Substitution Mutation at a Frequency of 1x10(-7) by Combining Two Genotypic Selection Methods, MutEx Enrichment and Allele-Specific Competitive Blocker PCR," Environmental and Molecular Mutagenesis, Vol. 32 p. 200-211, (1998).	
	C15	H. STEINGRIMSDOTTIR ET AL., "Development of new moleuclar procedures for the detection of genetic alterations in man," Mutation Research, Vol. 353, p. 109-121, (1996).	
	C16	TRANSGENOMIC, "Transgenomic Optimase Polymerase Delivers Highest Fidelity in PCR for WAVE System Analysis," (US). <a href="http://www.transgenomic.com/pdf/AN119u.pdf">http://www.transgenomic.com/pdf/AN119u.pdf</a> , (2002).	
	C17	DAVID SIDRANSKY, "Nucleic Acid-Based Methods for the Detection of Cancer," Science, Vol. 278, p. 1054-1059, (November 7, 1997).	
	C18	VINCENT L. WILSON ET AL., "Oncogenic Base Substitution Mutations in Circulating Leukocytes of Normal Individuals," Cancer Research, Vol. 60, p. 1830-1834, (April 1, 2000).	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.